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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/185,607	11/04/1998	SHUI-ON LEUNG	018733/0875	5589

7590 05/07/2004  
FOLEY & LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 200075300

EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/185,607

**Applicant(s)**

LEUNG ET AL

**Examiner**

Larry R. Helms

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-19,21-38,41,44,46,47,49 and 53-55 is/are pending in the application.
- 4a) Of the above claim(s) 30-37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-7,38 and 41 is/are allowed.
- 6) ☒ Claim(s) 8-19 and 21-29, 44, 46, 47, 49, 53-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/15/04 has been entered.
2. Claims 1, 4-19, 21-38, 41, 44, 46-47, 49, 53-55 are pending.
3. Claims 30-37 are withdrawn from consideration as being drawn to non-elected inventions.
4. NOTE: the species election is withdrawn in view of the withdrawn 103 rejection withdrawn in the appeal brief filed 10/15/03.
5. Claims 1, 4-19, 21-29, 38, 41, 44, 46-47, 49, 53-55 are under examination.
6. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

### ***Claim Objections***

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7. Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim recites wherein the ketone derivative is N-lev and N-lev fucose and the claim depends from claim 47 and 41 wherein the ketone derivative is already N-lev and N-lev fucose which was amended in this response.

***Rejections Withdrawn***

8. The rejection of claims 1, 4-14, 16-18, 38, 41, 44, and 47 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendments to the claims.

9. NOTE: The rejection of claims 19, 21-27, 29, 53-55 under 103 as obvious based on Shih et al (US 5,057,313) taken in view of Leung et al (Int J. Cancer 60:534-538, 1995) and Qu et al (Glycobiology 7:803-809, 1997) has already been dropped in view of arguments presented in the Appeal Brief filed 10/15/03.

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***Response to Arguments***

10. The rejection of claims 8-19, 21-29, 44, 46, 47, 49, 53-55 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The response filed 3/15/04 has been carefully considered but is deemed not to be persuasive. The response states that the examiner admits that the specification teaches a method that does not require oxidation but appears to discount his understanding that this is the case because it was gleaned from the background section of the specification and as one skill in the art the examiner recognized that the present method does not require oxidation and was developed to overcome the prior art and a skilled artisan has recognized that applicants were in position of glycosylated antibodies that possess 'a reactive ketone group that is not introduced by oxidation' (see page 17 of response). In response to this argument, there is nothing in the specification disclosing that the ketone is not introduced by oxidation. The entire section on pages 1-3 cite numerous example of prior art, but the specification does not disclose that the methods of the invention do not require oxidation or the antibodies are not produce by oxidation to produce a ketone. In fact the summary of the invention on page 3-5 does not exclude oxidation in any method. The summary states "it is, therefore, an object of the present invention to provide antibodies and antibody fragments that can be readily conjugated at specific sites to yield immunoreactive immunoconjugates" (see page 3-4)

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and "In accordance with other embodiments, the present invention provides a glycosylated antibody or antigen-binding antibody fragment having a reactive ketone group on the glycosylated site" (see page 5). Therefore, the specification does not exclude oxidation of the glycosylated antibodies in order to produce the antibody with the ketone reactive site.

Applicant is required to provide specific support for the limitation or remove it from the claims.

### ***Conclusion***

11. Claims 1, 4-7, 38, 41 are in condition for allowance.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.
13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

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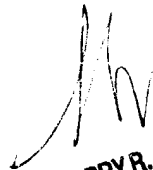
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Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER